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TRANSMITTAL FORM

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Application Number	10/696,487
Filing Date	October 29, 2003
First Named Inventor	Buchholz et al.
Art Unit	1642
Examiner Name	Ungar, Susan
Attorney Docket Number	21460

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

Communication

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature			
Printed name	Gene J. Yao		
Date	February 1, 2008	Reg. No.	47,193

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Signature			
Typed or printed name	Gene J. Yao	Date	February 1, 2008

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor(s): Buchholz et al.

Serial No. 10/696,487, filed October 29, 2003
(Ref. No. 21460)

Confirmation: 7548

Group: 1642

Examiner: Ungar, Susan, N.

For: **METHODS FOR DIAGNOSIS AND THERAPY OF PANCREATIC CANCER AND COMPOSITION USEFUL THEREIN**

COMMUNICATION

Nutley, New Jersey 07110
February 1, 2008

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The present Communication summarizes a telephone conference conducted by the undersigned with the Examiner on January 17, 2008.

During the conference, the Examiner proposed amendments which would place the claims in condition for allowance. The Examiner advised that, upon approval by the applicants, she would issue a Notice of Allowance with an Examiner's Amendment containing the subject amendments to the claims. Following the discussion, applicants agreed to the Examiner's proposed amendments. Specifically, the Examiner proposed the cancellation of claims 3, 13, and 17 and amending claims 1, 2, and 16 as follows.

1. A method for determining the presence or absence of pancreatic cancer in a patient comprising:

   (i) obtaining a biological sample from ~~a~~ said patient;

   (ii) detecting, in the sample, mRNA which is capable of being used in the production of ~~a~~ the sequence consisting of SEQ ID NO: 1; and

   (iii) comparing the amount of mRNA detected with a predetermined standard value indicating the decision line for tumor-induced or non-tumor-induced ~~UKW~~ expression or presence ~~in the cell~~ of mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 and therefrom determining the presence or absence of pancreatic cancer in the patient.

2. A process for determining whether or not a test sample of tissue or fluid of a patient contains pancreatic tumor cells, wherein the test sample and a second sample originating from non-pancreatic-tumor cells from the same individual or a different individual of the same species are used, wherein the samples are assayed for mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 with a probe selected from the group consisting of:

   (i) the nucleic acid consisting of SEQ ID NO: 1 or a fragment thereof, said fragment consisting of a nucleotide sequence comprising 50 contiguous nucleotides of SEQ ID NO: 1; and

   (ii) a nucleic acid consisting of a polynucleotide which is 100% complementary to said nucleic acid consisting of SEQ ID NO: 1 or said fragment thereof;

   wherein determination of approximately 15 fold to approximately 60 fold greater level of mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 in the test sample compared to the level of mRNA which is capable of being used in the production of the sequence consisting of

SEQ ID NO: 1 in the second sample, indicates that said test sample contains pancreatic cancer cells ~~which process comprises the following steps:~~

~~(a) incubating nucleic acids contained in each respective sample under stringent hybridization conditions with a nucleic acid probe which is selected from the group consisting of:~~

~~(i) the nucleic acid sequence consisting of SEQ ID NO: 1, or a fragment thereof, said fragment comprising 50 contiguous nucleotides of SEQ ID NO: 1;~~

~~(ii) a nucleic acid sequence which is 100% complementary to any nucleic acid sequence of (i);~~

~~(iii) a nucleic acid sequence which is capable of hybridizing under high stringent hybridization conditions with the sequence of (i); and~~

~~(iv) a nucleic acid sequence which is capable of hybridizing under high stringent hybridization conditions with the sequence of (ii);~~

~~(b) determining the approximate amount of hybridization of nucleic acids present in each respective sample with said probe, and~~

~~(c) comparing the approximate amount of hybridization present in said test sample to an approximate amount of hybridization present in said second sample to identify whether or not the test sample contains an approximately 15-fold to approximately 60-fold greater level of hybridization than does said second sample and therefrom determining whether the test sample contains pancreatic tumor cells;~~

~~said stringent hybridization conditions being conditions involving washing said nucleic acids with a solution of 5x SSC, 0.5% SDS, 1.0 mmol/1 EDTA, pH 8.0, then hybridizing said nucleic acids at 50 to 60°C in 5x SSC overnight, then washing said nucleic acids at room temperature for 40 minutes with 2x SSC containing 0.1% SDS and afterwards washing said nucleic acids with 0.1x SSC, 0.1% SDS at 50°C for 40 minutes with one change of fresh solution;~~

~~said high stringent hybridization conditions being conditions involving washing said nucleic acids with a solution of 5x SSC, 0.5% SDS, 1.0 mmol/1 EDTA, pH 8.0, then hybridizing said nucleic acids at 65 to 70°C in 5x SSC overnight, then washing said nucleic acids at room temperature for 40 minutes with 2x SSC containing 0.1% SDS and afterwards washing said nucleic acids with 0.1x SSC, 0.1% SDS at 50°C for 40 minutes with one change of fresh solution~~.

16. A process according to claim 2 ~~3~~ wherein said nucleic acid probe is the nucleic acid shown in SEQ ID NO:1 or a nucleic acid which is 100% complementary to said sequence.

In addition to the above, the Examiner advised that the Office is not in receipt of a certified copy of the European Application No. 02024539.5, which serves as the priority document for the present application. While applicants had filed such a certified copy in the Office on November 8, 2004, the Examiner advised that the copy in the Office's file related to a different application. Applicants maintain that a certified copy of the `539 application was indeed filed in the Office; nevertheless, applicants have filed a second certified copy of the `539 application on January 28, 2008. Applicants hereby request, therefore, that the priority claim based on the `539 European application be recognized.

In view of the above, applicants await the issuance of a Notice of Allowance with an Examiner's Amendment containing the aforementioned amendments.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

The Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,

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